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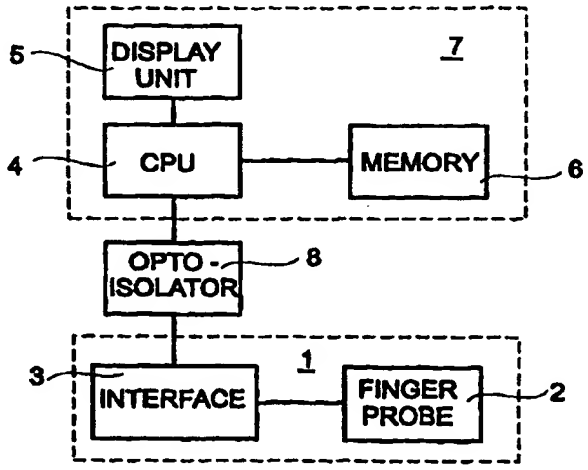

(57) Abstract

A Bioenergetic Data Collection Apparatus utilizing a modified oximeter (1) to collect signals characteristic of blood flow in terminal tissue, such as a finger tip (12). A processing means (7) in signal connection with the modified oximeter (1) receives and analyzes the signals to produce pulse waveforms, or a pulse waveform sequence, that is displayed on a high resolution video display (5). An isolation means (8) is provided between the modified oximeter (1) and the processing means (7) to ensure no lethal voltages can threaten a patient. A variety of aids are provided to assist an appropriately skilled practitioner to make a prognosis from the displayed data. The tools include measurement of the ratio of heart activity to heart rest, variation in systolic pulse amplitude, variation in pulse shape, etc.

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"BIOENERGETIC DATA COLLECTION APPARATUS"

FIELD OF THE INVENTION

This invention relates to a method and apparatus for the collection of biomedical data. In particular, it relates to a bioenergetic approach to the evaluation of observed cardiovascular response as recorded in terminal tissue, such as the fingertip. The invention finds primary application with humans but may also be applied to animals.

BACKGROUND TO THE INVENTION

Biomedical data can be collected using electronic instruments that utilize electromagnetic energy in various ways. A useful summary of known devices and techniques has been presented by Dr. Dennis W Remmington to the Joint Committee Meeting of the Utah State Medical Association and published in July 1990. He summarises the known devices in two categories: instruments which measure passive electrical energy, and instruments which measure response to stimuli.

The first category includes instruments such as the electrocardiograph (ECG), the electroencephalograph (EEG), Chinese electric pulse testing, and Chinese gastrointestinal analysis.

In the second category are instruments that measure response to stimuli, such as galvanic skin response devices, and instruments that measure response to electromagnetic stimuli, such as electromyelography, brain stem audiometry, magnetic resonance imaging (MRI) and electroacupuncture according to Voll (EAV).

The galvanic skin response technique measures the electrical conductance between two electrodes placed on the skin. The patient is then subjected to various stimuli, and any change in skin conductance is recorded. Any stimuli causing increased sweat production will increase the conductance and give a change in the readings, which are usually recorded on a graph.

In the EAV method a low voltage electrical charge is introduced into the body, and the precise level of electric current conducted through the

acupuncture points are measured. Information about various organ systems and musculoskeletal regions is obtained by the level of the readings.

The known devices have proven useful to various degrees in providing biomedical data to assist medical practitioners in diagnosis. However, the majority of the known techniques are invasive and require the application of electric current to the patient. Furthermore, the known techniques are subjective in nature and subject to wide variation in interpretation of indicative measures. A method and apparatus for passively collecting bioenergetic data is desirable.

The collection of bioenergetic data, such as pulse rate, by monitoring of blood movement in the fingertip is known. Common devices for performing this function comprise a red or infrared light source and detector. The light incident on the fingertip penetrates a small distance into the fingertip and is modulated by absorption in the blood in the capillaries. A portion of the light is reflected or transmitted and this is measured by the detector. Thus the signal from the detector mimics the flow of blood through the fingertip.

These devices are not limited to use at the fingertip or with humans. Devices for use with animals commonly measure blood movement at the ear lobe, lip or tongue.

The majority of the applications of the device described above are for simple monitoring of pulse rate. In some applications, the signals from the device are analysed in more detail to separately identify the systolic and diastolic pulses.

In recent times the devices have become more sophisticated with the advent of more intense light sources and more sensitive detectors. It is now possible to estimate the partial pressure of oxygen in the body by monitoring absorption of infrared light in the blood and making a number of assumptions. Devices performing this function are generally known as oximeters.

The inventors have found that a great deal more information can be obtained by monitoring blood flow in the fingertip than has previously been

realised.

OBJECT OF THE INVENTION

It is an object of the present invention to provide an apparatus for the monitoring and evaluation of observed cardiovascular response.

A further object of the present invention is to provide a method of monitoring and evaluating cardiovascular response.

Further objects will be evident from the following description.

DISCLOSURE OF THE INVENTION

In one form, although it need not be the only or indeed the broadest form, the invention resides in an apparatus for the collection of bioenergetic data comprising:

monitoring means adapted to produce signals characteristic of blood flow;

processing means in signal connection with said monitoring means and adapted to receive and analyse said signals to indicate the bioenergetic status of a body; and

display means adapted to display the bioenergetic status so indicated.

In preference the apparatus further comprises an isolation means in signal connection with the monitor means and processing means. The isolation means preferably provides electrical isolation between the monitoring means and the processing means so as to ensure that the relatively high voltages in the processing means cannot be transmitted to a patient through the monitoring means.

In preference the monitoring means comprises an oximeter adapted to monitor blood flow in an extremity, such as a fingertip or ear lobe. The oximeter preferably comprises a light source, detector means and interface means. The detector is preferably a photodiode. The light source may be a light emitting diode (LED) or diode laser emitting infrared or visible radiation. Preferably, there are two light sources, one emitting infrared radiation and one emitting visible radiation. The signals from the detector

are indicative of the nature of the blood flow in the extremity. The interface means performs preliminary processing of the signals from the detector including converting the analogue detector signals to digital signals suitable for the processing means.

In preference the processing means is a microprocessor programmed to measure characteristics of the received signals. The measured characteristics include such characteristics as:

- the ratio of heart activity to heart rest
- the variation in systolic pulse amplitude over time
- the ratio of systolic pulse amplitude to diastolic amplitude
- variation in shape from pulse to pulse
- variation in pulse shape over time.

In preference the bioenergetic status of the body is indicated according to such functions as:

- pulse rate
- oxygen saturation in terminal tissue (SpO_2)
- blood flow rate
- elasticity of blood vessels
- strength and regularity of the heart beat
- cardiac sufficiency
- cardiac valve activity
- cardiac or vascular metabolic abnormalities
- cell energy change
- latent hypertension
- myocardium damage
- cardiac or vascular inflammation
- allergic reactions
- immune system response changes
- pulmonary/cardiac function variations
- bioenergetic reactions at lining of intestine

The display means is suitably a high resolution video display adapted to display graphical and alphanumeric data. The graphical data preferably

includes a representation of the measured pulse shape or a series of measured pulses. The alphanumeric data preferably includes indications of one or more of the above characteristics or functions.

In preference, the apparatus further comprises memory means in signal connection with the processing means. The memory means may provide transient storage of data, permanent storage of data or both.

The apparatus may further comprise an EKG module to provide an electrical readout of the heart function for an objective profile of the cardiac function, an allergy module for providing an objective computer based evaluation and assessment of electrodermal readings of known allergens by registering before and after microvoltage changes in response to allergens, and a pulse blood pressure module for providing diastolic, systolic and mean arterial pressure.

In a further form the invention resides in a method of collecting bioenergetic data of a body including the steps of:

transmitting visible and infrared radiation into terminal tissue;

measuring a voltage signal proportional to visible and infrared radiation transmitted through the terminal tissue;

converting the voltage signal to a digital signal;

passing the digital signal to a processing means;

processing the digital signal in the processing means to produce a displayable waveform; and

displaying the displayable waveform on a display means.

The method may include the further steps of analysing the waveforms to provide indicative measures of the cardiovascular health of the body.

BRIEF DETAILS OF THE DRAWINGS

To further assist in understanding the invention reference will be made to the following drawings in which:

FIG 1 is a block diagram of the components of an apparatus for collection of bioenergetic data;

FIG 2 is a detailed sketch of an oximeter;

FIG 3 is a schematic block diagram of the interface of the apparatus;

FIG 4 shows a comparison of the waveform of a healthy person with a not so healthy person;

FIG 5 is a trace showing the heart activity and amplitude ratio measurements;

FIG 6 is a trace showing an ATP ramp measurement;

FIG 7 is a trace showing an expansion of a dichotic notch region;

FIG 8 is a trace showing an expansion of a systolic pulse;

FIG 9 shows a comparison of a waveform for a patient before and after exposure to a therapeutic magnetic field;

FIG 10 is an expanded section of FIG 9;

FIG 11 is a comparison of a waveform for a patient before and after exposure to an allergen;

FIG 12 is a flowchart of the operation of the apparatus; and

FIG 13 is a block diagram of additional modules for the apparatus.

DETAILED DESCRIPTION OF THE DRAWINGS

In the drawings, like reference numerals refer to like parts.

Referring now to the drawings in detail there is shown in FIG 1 a block diagram of a bioenergetic data collection apparatus according to a first embodiment. The apparatus comprises a monitor means 1, which in the preferred embodiment is an oximeter comprising a finger probe 2 and interface 3. Signal processing is performed in processing means 4. Associated with the processing means 4 is a display unit 5 and memory 6. In the preferred embodiment the processing means 4, display unit 5 and memory 6 together comprise a personal computer 7. The personal computer 7 may conveniently be a laptop computer thereby making the whole apparatus portable.

The interface 3 is in signal connection with an isolation means, such as opto-isolator 8, which is in signal connection with the processing means 4. The interface 3 has its own power supply so the only requirement for connection between the oximeter 3 and personal computer 7 is for the transmittal of signals from the interface 3 to the computer 7 via the opto-isolator 8. The opto-isolator 8 primarily provides electrical isolation between the interface 3 and the processing means 4 to avoid any risk of electrical injury to persons using the apparatus.

The operation of the pulse monitor and finger probe are shown in more detail in FIG 2. A commercially available device such as a model 71000A2 pulse oximeter from BCI International may be modified for use in the bioenergetic data collection apparatus. The finger probe comprises an infrared light source 9, a red light source 10 and a detector 11. In normal operation the oximeter determines SpO_2 and pulse rate by passing two wavelengths of light, one red and one infrared, through body tissue 12 to the photodetector 11. The light sources are pulsed and the photodetector signal is sampled at 120Hz. During measurement, the signal strength resulting from each light source depends on the colour and thickness of the body tissue, the probe placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.

The oximeter processes these signals, separating the time invariant parameters (tissue thickness, skin colour, light intensity, and venous blood) from the time variant parameters (arterial volume and pO_2) to identify the pulse rate and calculate oxygen saturation. Oxygen saturation calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

The signal from the interface 3 is a time varying voltage with fast amplitude changes. The processing means 4 requires signals in a digital form so the interface 3 is required to sample and digitise the signal from the probe 2. Prior art devices have applied a relatively course digitising filter which has resulted in the loss of information rich high frequency components

of the signal.

The commercially available oximeter requires two primary modifications for use in the bioenergetic data collection apparatus. Firstly, the output port of the interface 3 is adapted for connection to a standard serial port of a personal computer. Secondly, the bandpass of the interface 3 is modified to allow high frequency components to be transmitted to the processing means. Commercial devices routinely include a band-pass filter to remove high frequency components and thereby obtain a more stable reading of the relatively low frequency pulse rate and SpO_2 values. The interface 3 provides a local readout of pulse and SpO_2.

The inventor has found it useful to filter out very low frequency signals that are caused by movement of the patient. Although the filtering can be performed in hardware by modification of the oximeter it is convenient to provide software filtering in the processing means.

A schematic block diagram of the interface 3 is shown in FIG 3. A standard microprocessor kernel 13 is formed by microprocessor 14, RAM 15 and EPROM 16. Communication is provided on address bus 17. A current to voltage converter 18 converts the current output of the detector 11 to a voltage readable by the analogue to digital converter 19. The analogue to digital converter 19 performs a 12-bit conversion and places the digital result on data bus 20. The microprocessor 14 analyses the data to provide the local display and outputs the digital data through serial port 21.

The processing means 4 may be a personal computer programmed to analyze the signals received from the interface 3. The personal computer may conveniently be a laptop computer which facilitates mobility of the apparatus. In the described embodiment the display means 5 is included as the monitor of the personal computer or laptop computer. In an alternative embodiment a purpose built processing means may be packaged into a compact container.

The apparatus may be operated in two main modes. In a first mode the apparatus monitors and collects data on the pulse of a subject. In this mode the apparatus is able to provide data in a form that facilitates diagnosis

by a skilled medical practitioner. An example of the graphical data obtainable in this mode is given in FIG 4. Fig 4a shows a pulse trace recorded for a 20 year old male in good physical condition. The systolic 22 and diastolic 23 pulses are well-defined and clean. In contrast, Fig 4b shows a pulse trace for an individual in poor physical condition. The systolic and diastolic traces are poorly defined and very irregular. This trace indicates serious vascular problems.

Further analysis can be conducted on the recorded traces. Fig 5 is a screen dump of a display demonstrating the calculation of heart activity. The X-axis 24 is marked in seconds and the Y-axis 25 is in arbitrary units. Identifying information including the date, file number, scale, SpO_2 and pulse rate are printed below the X-axis.

Heart activity is defined as the ratio of heart action to heart rest, which in the figure is calculated by D-B/H-B. The result of the calculation is shown on the screen at 26. The value provides useful information to a physician to aid in diagnosis. An amplitude ratio can also be calculated. The amplitude ratio is defined as C-A/E-A. The result may also be shown on screen.

Fig 6 shows how the apparatus can be used to display and compare the ATP ramp angle. The angle of dotted line 27 can be set by the physician at the ATP ramp angle considered to be ideal for the patient and situation. The variation of a trace from the ideal angle is immediately evident. In the example of Fig 6 the region 28 is good but the other regions, such as 29, deviate to a small degree. It will be appreciated that the example of Fig 4b would show a marked deviation.

Regions of the pulse trace can be windowed and expanded as demonstrated in Fig 7. In Fig 7 the region around the dichotic notch has been expanded to show the high frequency components. It is generally accepted that this region of the pulse trace is indicative of gastrointestinal tract health. A bowel irritation may be manifest in an increase in high frequency components in this region. If every pulse in the trace shows a 'bump' in the ATP ramp region there is likely to be a colon problem. If the 'bump' is intermittent, the problem is probably with ATP production (eg

fatigue). The apparatus provides a display of this region to assist the physician to make a correct diagnosis.

In Fig 8 the region around the top of the systolic pulse trace is enlarged. The shape of the trace in this region is generally accepted as indicative of the health of the aortic valve. A double peak is bad, whereas a single peak, such as 30, indicates good aortic valve condition. The physician can also obtain an estimate of the volumetric blood flow by measuring the height and width of the systolic pulse. This may also be used to diagnose overall heart condition.

In a second mode the data before a change can be stored in memory 6 and compared with data obtained after the change and an analysis provided. The change may be the application of a therapeutic magnetic field such as could be applied by the device described in United States patent number 5527259. Fig 9 indicates the differences that can be observed before and after the application of therapeutic magnetic fields.

In Fig 9 the entire trace acquired over 30 seconds is shown. The lower trace, trace B, is the first acquired trace prior to application of a therapeutic magnetic field. The full trace is useful for showing pulse trends such as the variation in the pulse baseline 31. It is clear in the lower trace that there is considerable variation in the baseline. In contrast the baseline 32 in the upper trace is relatively flat.

The scale can be expanded to highlight a subset of pulses. The first five seconds of the traces in Fig 9 are shown in Fig 10. This mode of display is useful for identifying changes in the pulse shapes as opposed to the pulse trends identified from Fig 9. It is clear from Fig 10 that the 'bumps' 33 evident in the ATP ramp of the lower trace are gone from the upper trace after application of therapeutic magnetic fields.

A comparison between traces can also be made to detect the impact of detrimental influences on the body. One such application is the identification of allergic response. Fig 11 shows a comparison of traces taken without (lower trace) and with (upper trace) allergenic influence. The allergenic influence may be applied by a patient simply holding a vial

containing allergenic materials. Kits of allergens can be obtained from homeopathic suppliers such as the Practitioner Test Kit obtainable from Brauer Biotherapies Pty Ltd. Fig 11 clearly shows a disruption of the ATP ramp as indicated by 34a in the lower trace and 34b in the upper trace. This disruption can be used by a physician to diagnose allergic reaction to different allergens.

A flow chart of the operation of the apparatus is shown in Figs 12a, 12b and 12c. An initial set-up routine sets up the apparatus according to parameters selected by the user. These parameters include the communications, display and analysis parameters (such as ATP ramp angle).

The name of the patient is keyed into the apparatus for data storage purposes. If the patient is a new patient a new database is opened. If the program detects the name of an existing patient the historical data for that patient is retrieved.

Once the equipment is set-up and the patient information is entered, data collection is commenced. A sub-routine checks synchronisation between the oximeter and the processing means. If the units are not synchronised or synchronicity is lost, the data collection process is recommenced.

The collected data is high pass filtered, displayed on the display means in real time and stored in a temporary buffer. The pulse rate and SpO_2 values are read from the oximeter interface and displayed. Data collection continues for a timed period or until terminated by the operator.

Upon completion of data collection the patient record number is advanced by one and the data is saved to the patient data base. Notes can be entered by the operator if desired.

Comparative data is then retrieved and displayed on the display means with the recorded data. The comparative data may be previous data from the same or a different patient or may be standard data from a compiled library. The operator is able to make a number of comparisons between the new recorded data and the other data on screen. The waveforms can be

shifted or scaled as desired.

The patient records or pati nt data can be deleted or renamed if required. Certain fragments of the waveforms can be zoomed for calculation of indicative diagnostic values. Indicative diagnostic ratios include the heart activity or time ratio and the amplitude ratio.

The ATP ramp line may be drawn by using a mouse or cursor keys to move a cursor to the start of an ATP ramp. The line is drawn at an angle provided at set-up.

A printer interface is provided in the software so that the waveforms and notes may be printed as required. Help files are also provided to assist users of the apparatus. The help files provide details of operating procedures as well as descriptions of common waveforms.

The apparatus may incorporate additional modules to extend the data collection functions to include a diagnostic capability. Fig 13 is a schematic of the modular nature of the invention. The primary module, as described in detail above, is known by the inventors as the Magnagraph ™ 35. An EKG Module 36 may interface to the Magnagraph ™ 35 to provide an electrical readout of the heart function which, added to the Magnagraph ™ physical and mechanical evaluation, renders a complete and objective profile of the cardiac function. A Pulse Blood Pressure Module 37 provides diastolic, systolic and mean arterial pressure, creating a comprehensive and objective evaluation of the profile of the cardiac function. An Allergy Module 38 provides an objective computer based evaluation and assessment of electrodermal readings of known allergens by registering before and after microvoltage changes in response to allergens.

Previously, the allergen response described earlier could only be interpreted subjectively. The Allergy Module 38 provides objective evaluation by comparing measured waveforms with a library of known responses.

It will be appreciated that the apparatus and method described herein are useful for collecting and displaying bioenergetic data collected from a body. Although the description has been in terms of application to a human

body it may equally be applied to animals. It will be further appreciated that the collected data can be analysed to varying degrees to provide information of greater value to a medical practitioner or veterinarian. It should be emphasised that the invention is not a prognostic device but only provides data for further consideration by an appropriately skilled practitioner.

The preferred embodiments described herein are intended to illustrate the principles of the invention, but not to limit its scope. Other embodiments and variations to the preferred embodiments may be evident to those skilled in the art and may be made without departing from the spirit and scope of the invention.

CLAIMS

1. An apparatus for the collection of bioenergetic data comprising:

monitoring means adapted to produce signals characteristic of blood flow;

processing means in signal connection with said monitoring means and adapted to receive and analyze said signals to indicate the bioenergetic status of a body; and

display means adapted to display the bioenergetic status so indicated.

2. The apparatus of claim 1 further comprising an isolation means in signal connection with the monitor means and processing means, said isolation means providing electrical isolation between the monitoring means and the processing means.

3. The apparatus of claim 1 wherein the monitoring means comprises an oximeter adapted to monitor blood flow in an extremity, such as a fingertip or ear lobe.

4. The apparatus of claim 3 wherein the oximeter comprises at least one light source, detector means and interface means.

5. The apparatus of claim 4 wherein the light source is a light emitting diode (LED) or diode laser emitting infrared or visible radiation.

6. The apparatus of claim 5 comprising two light sources, one emitting infrared radiation and one emitting visible radiation.

7. The apparatus of claim 4 wherein the detector is a photodiode, said photodiode producing signals responsive to light received from the light source, said signals being indicative of the nature of the blood flow in the extremity.

8. The apparatus of claim 4 wherein the interface means performs preliminary processing of the signals from the detector means including converting the analogue detector signals to digital signals suitable for processing by the processing means.

9. The apparatus of claim 1 wherein the processing means is a microprocessor programmed to measure characteristics of the signals.

10. The apparatus of claim 9 wherein the measured characteristics are

chosen from a list of measurable characteristics including: the ratio of heart activity to heart rest; the variation in systolic pulse amplitude over time; the ratio of systolic pulse amplitude to diastolic amplitude; variation in shape from pulse to pulse; and variation in pulse shape over time.

11. The apparatus of claim 1 wherein the bioenergetic status of the body is indicated according to indicative functions chosen from a list including: pulse rate; oxygen saturation in terminal tissue (SpO_2); blood flow rate; elasticity of blood vessels; strength and regularity of the heart beat; cardiac sufficiency; cardiac valve activity; cardiac or vascular metabolic abnormalities; cell energy change; latent hypertension; myocardium damage; cardiac or vascular inflammation; allergic reactions; immune system response changes; pulmonary/cardiac function variations; and bioenergetic reactions at lining of intestine.

12. The apparatus of claim 1 wherein the display means is a high resolution video display adapted to display graphical and alphanumeric data.

13. The apparatus of claim 12 wherein the graphical data includes a representation of measured pulse shape or a series of measured pulse shapes.

14. The apparatus of claim 12 wherein the alphanumeric data includes indications of one or more measurable characteristics or indicative functions.

15. The apparatus of claim 1 further comprising an EKG module providing an electrical readout of heart function.

16. The apparatus of claim 1 further comprising an allergy module providing an objective computer based evaluation and assessment of electrodermal readings of known allergens by registering before and after microvoltage changes in response to said known allergens.

17. The apparatus of claim 1 further comprising a pulse blood pressure module for providing diastolic, systolic and mean arterial pressure.

18. A method of collecting bioenergetic data of a body including the steps of:

transmitting visible and infrared radiation into terminal tissue; measuring a voltage signal proportional to visible and infrared

radiation transmitted through the terminal tissue;

converting the voltage signal to a digital signal;

passing the digital signal to a processing means;

processing the digital signal in the processing means to produce a displayable waveform; and

displaying the displayable waveform on a display means.

19. The method of claim 18 further including the steps of analysing the waveforms to provide indicative measures of the cardiovascular health of the body.

AMENDED CLAIMS
[received by the International Bureau on 20 May 1997 (20.05.97);
original claims 1-19 replaced by new claims 1-19
(3 pages)]

1. An apparatus for the collection of bioenergetic data indicative of bioenergetic status comprising:

optical monitoring means adapted to produce time-varying signals characteristic of cardiovascular response, said time-varying signals including high frequency components;

processing means in signal connection with said monitoring means and adapted to extract bioenergetic data from the time-varying signals and analyse said bioenergetic data to indicate bioenergetic status; and

display means adapted to display the bioenergetic status so indicated.

2. The apparatus of claim 1 further comprising an isolation means in signal connection with the optical monitor means and processing means, said isolation means providing electrical isolation between the monitoring means and the processing means.

3. The apparatus of claim 1 wherein the optical monitoring means is adapted to monitor blood flow in an extremity, such as a fingertip or ear lobe, and comprises at least one light source, at least one optical detection means and interface means.

4. The apparatus of claim 3 wherein said at least one light source is a light emitting diode (LED) or diode laser emitting infrared or visible radiation.

5. The apparatus of claim 4 comprising a first light source emitting infrared radiation and a second light source emitting visible radiation.

6. The apparatus of claim 3 wherein said at least one detector is a photodiode, said photodiode producing time-varying signals responsive to light received from said at least one light source, said time-varying signals being characteristic of cardiovascular response evident in blood flow in terminal tissue at the extremity.

7. The apparatus of claim 5 comprising a photodiode producing time-varying signals responsive to light received from said first light source and producing time-varying signals responsive to light received from said second light source.

8. The apparatus of claim 3 wherein the interface means performs preliminary processing of the time-varying signals from the detector means including converting analogue signals from said at least one detector to digital signals suitable for processing by the processing means.

9. The apparatus of claim 1 wherein the processing means is a microprocessor programmed to perform an algorithm to calculate bioenergetic date from said time-varying signals and analyse said bioenergetic data to indicate bioenergetic status.

10. The apparatus of claim 1 wherein the bioenergetic data includes one or more measurable characteristics chosen from a list including : ATP ramp angle, the ratio of heart activity to heart rest; the variation in systolic pulse amplitude over time; the ratio of systolic pulse amplitude to diastolic amplitude; variation in shape from pulse to pulse; and variation in pulse shape over time.

11. The apparatus of claim 1 wherein the bioenergetic status of the body is indicated according to indicative functions chosen from a list including: pulse rate; oxygen saturation in terminal tissue (SpO_2); blood flow rate; elasticity of blood vessels; strength and regularity of the heart beat; cardiac sufficiency; cardiac valve activity; cardiac or vascular metabolic abnormalities; cell energy change; latent hypertension; myocardium damage; cardiac or vascular inflammation; allergic reactions; immune system response changes; pulmonary/cardiac function variations; and bioenergetic reactions at lining of intestine.

12. The apparatus of claim 1 wherein the display means is a high resolution video display adapted to display graphical and alphanumeric data.

13. The apparatus of claim 12 wherein the graphical data includes a representation of measured pulse shape or a series of measured pulse shapes.

14. The apparatus of claim 12 wherein the alphanumeric data includes indications of one or more measurable characteristics or indicative functions.

15. The apparatus of claim 1 further comprising an EKG module in signal connection with said processing means, said EKG module adapted to produce signals characteristic of heart function, wherein said processing means analyses said bioenergetic data and said signals characteristic of heart function to indicate bioenergetic status.

16. The apparatus of claim 1 further comprising an allergy module in signal connection with said processing means, said allergy module comprising recording means adapted to record electrodermal readings in the form of before and after microvoltage changes occurring in response to known allergens, and analysis means adapted to provide signals characteristic of allergic reaction to known allergens by analysing said electrodermal readings and performing an objective computer based evaluation and assessment, wherein said processing means analyses said bioenergetic data and said signals characteristic of allergic reaction to indicate bioenergetic status.

17. The apparatus of claim 1 further comprising a pulse blood pressure module in signal connection with said processing means, said pulse blood pressure module adapted to provide signals characteristic of pulse pressure including diastolic, systolic and mean arterial pressure, wherein said processing means analyses said bioenergetic data and said signals characteristic of pulse pressure to indicate bioenergetic status.

18. A method of collecting bioenergetic data including the steps of :

transmitting visible and infrared radiation into terminal tissue;

measuring a voltage signal proportional to visible and infrared radiation transmitted through the terminal tissue;

converting the voltage signal to a digital signal;

passing the digital signal to a processing means;

processing the digital signal in the processing means to produce a displayable waveform; and

displaying the displayable waveform on a display means.

19. The method of claim 18 further including the steps of analysing the wav forms to provide indicative measur s of cardiovascular health.

1/14

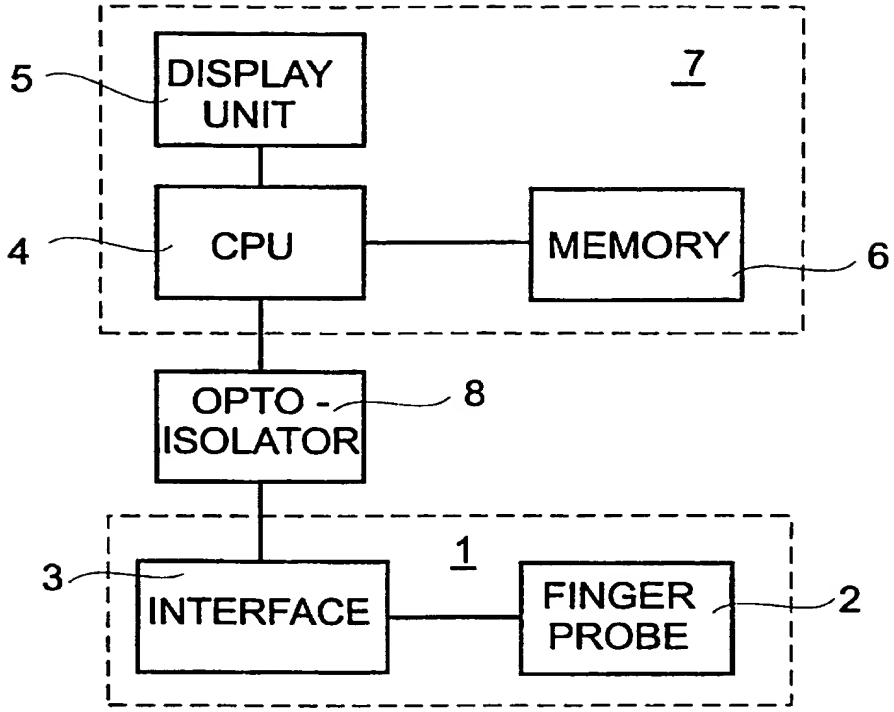

FIG. 1

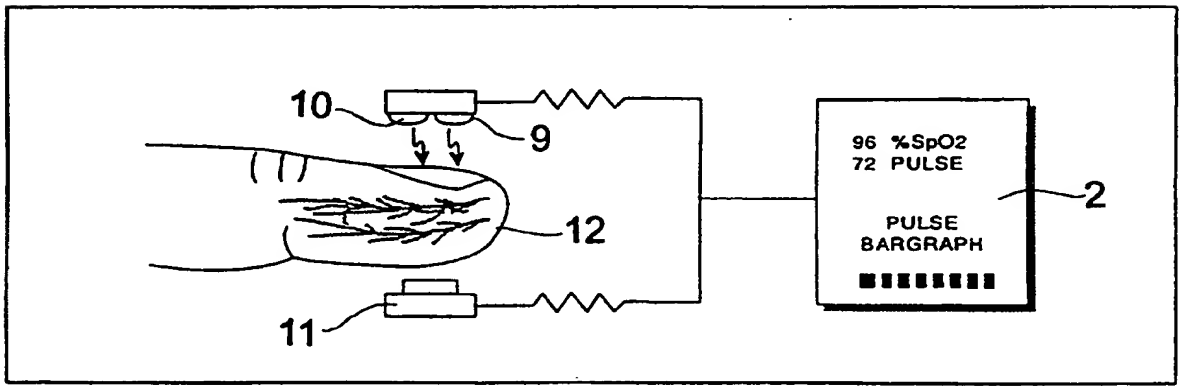

FIG. 2

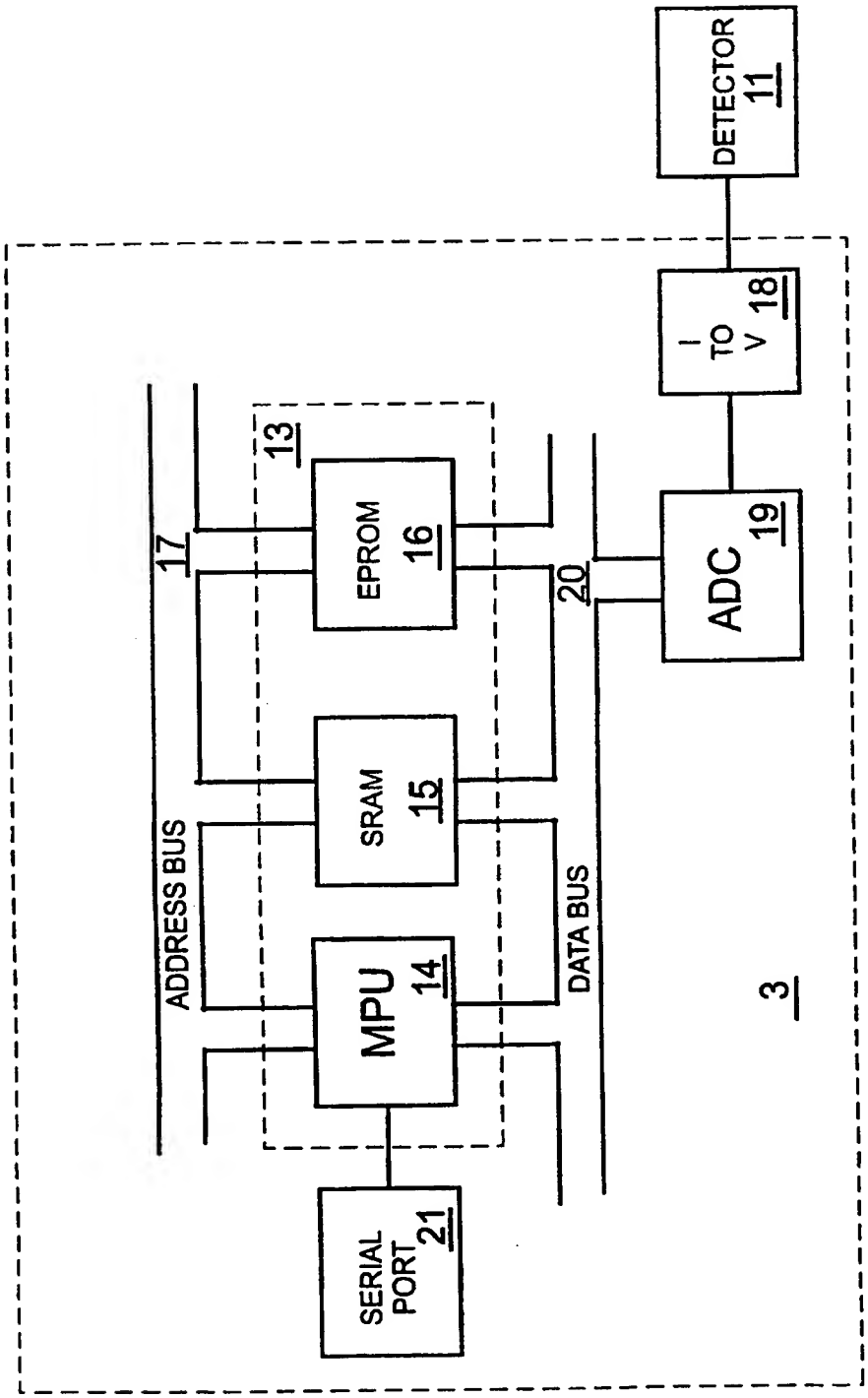
DETECTOR
11
I TO V
18
ADC
19
20
EPROM
16
13
17
SRAM
15
ADDRESS BUS
DATA BUS
MPU
14
SERIAL PORT
21
3

FIG. 3

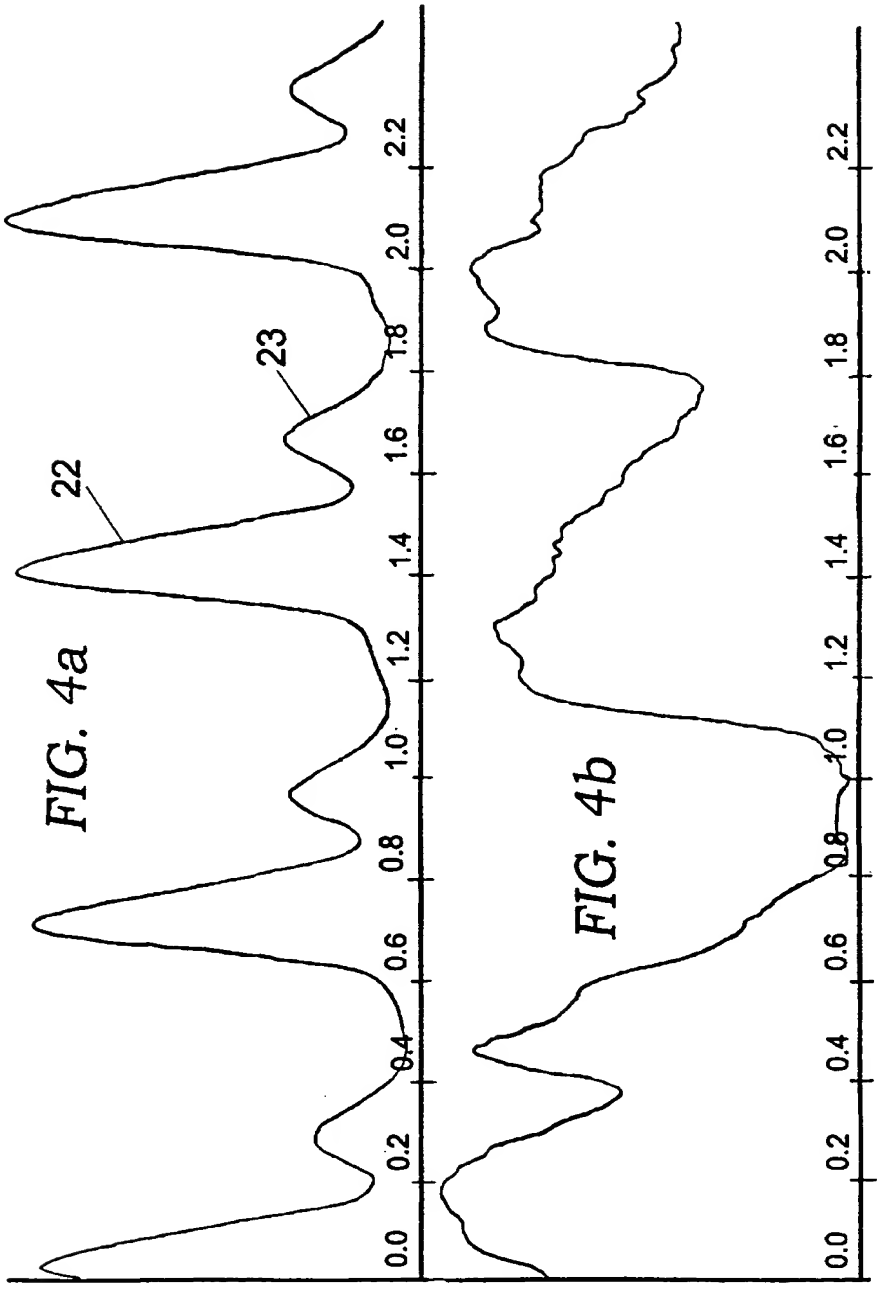

FIG. 4a

FIG. 4b

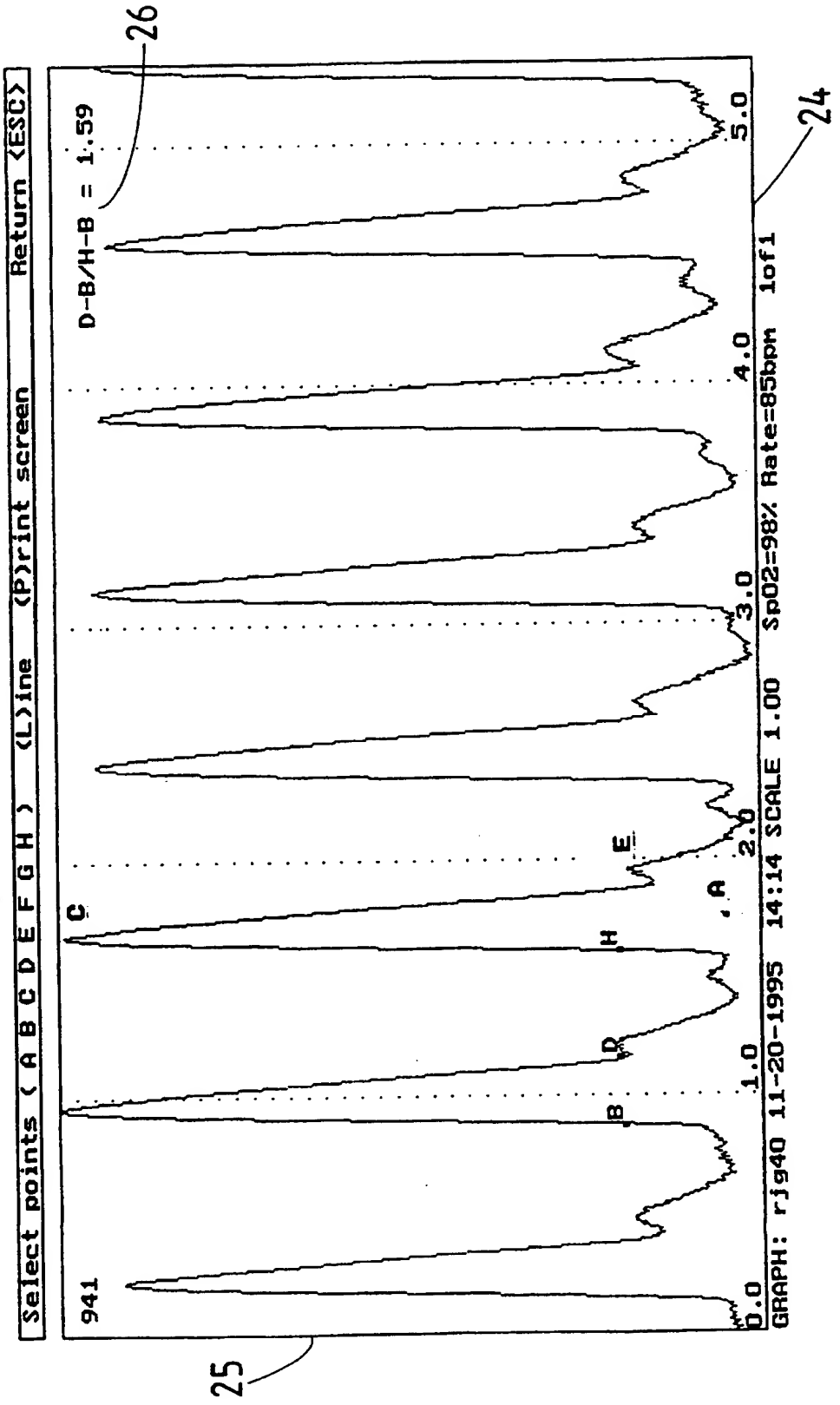
Select points (A B C D E F G H) (L)ine (P)rint screen Return <ESC>
D-B/H-B = 1.59
26
24
25
941
A
B
C
D
E
H
0.0
1.0
2.0
3.0
4.0
5.0
GRAPH: rjg40 11-20-1995 14:14 SCALE 1.00 SpO2=98% Rate=85bpm 1of1

FIG. 5

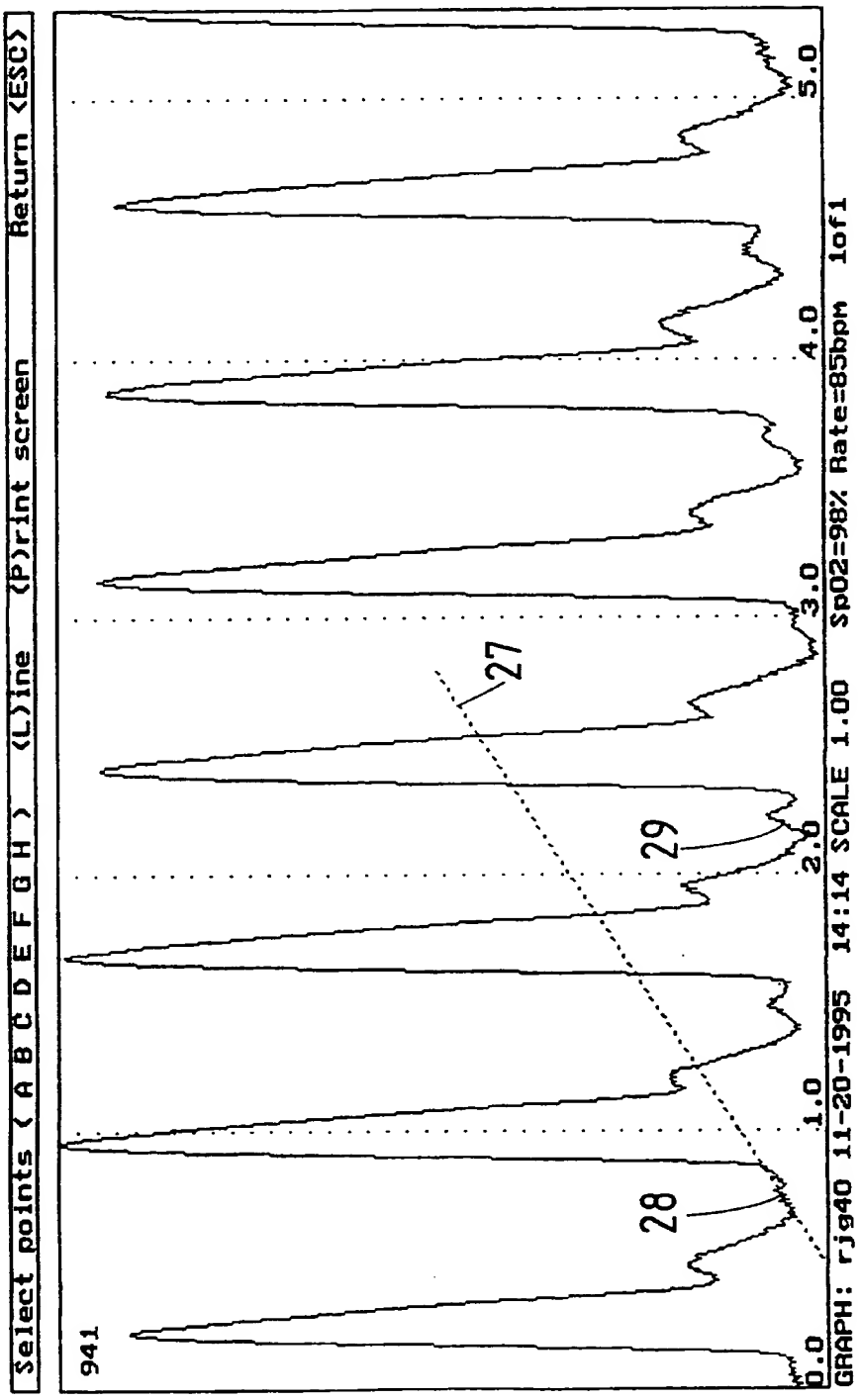
Select points <A B C D E F G H> <L>ine <P>rint screen Return <ESC>
941
27
29
28
0.0
1.0
2.0
3.0
4.0
5.0
GRAPH: rjg40 11-20-1995 14:14 SCALE 1.00 SpO2=98% Rate=85bpm 1of1

FIG. 6

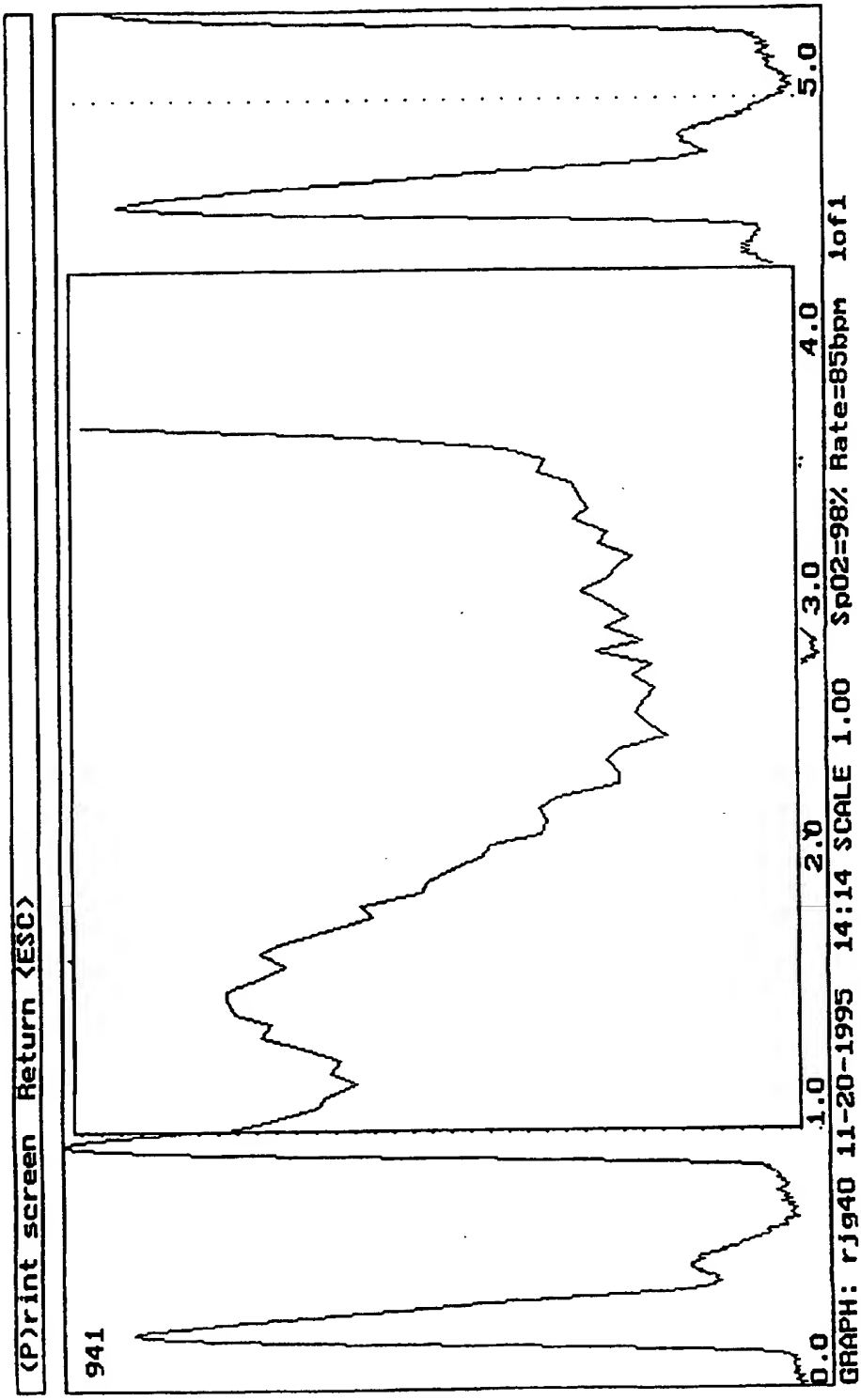
(P)rint screen Return <ESC>
941
0.0
1.0
2.0
3.0
4.0
5.0
GRAPH: rjg40 11-20-1995 14:14 SCALE 1.00 SpO2=98% Rate=85bpm 1of1

FIG. 7

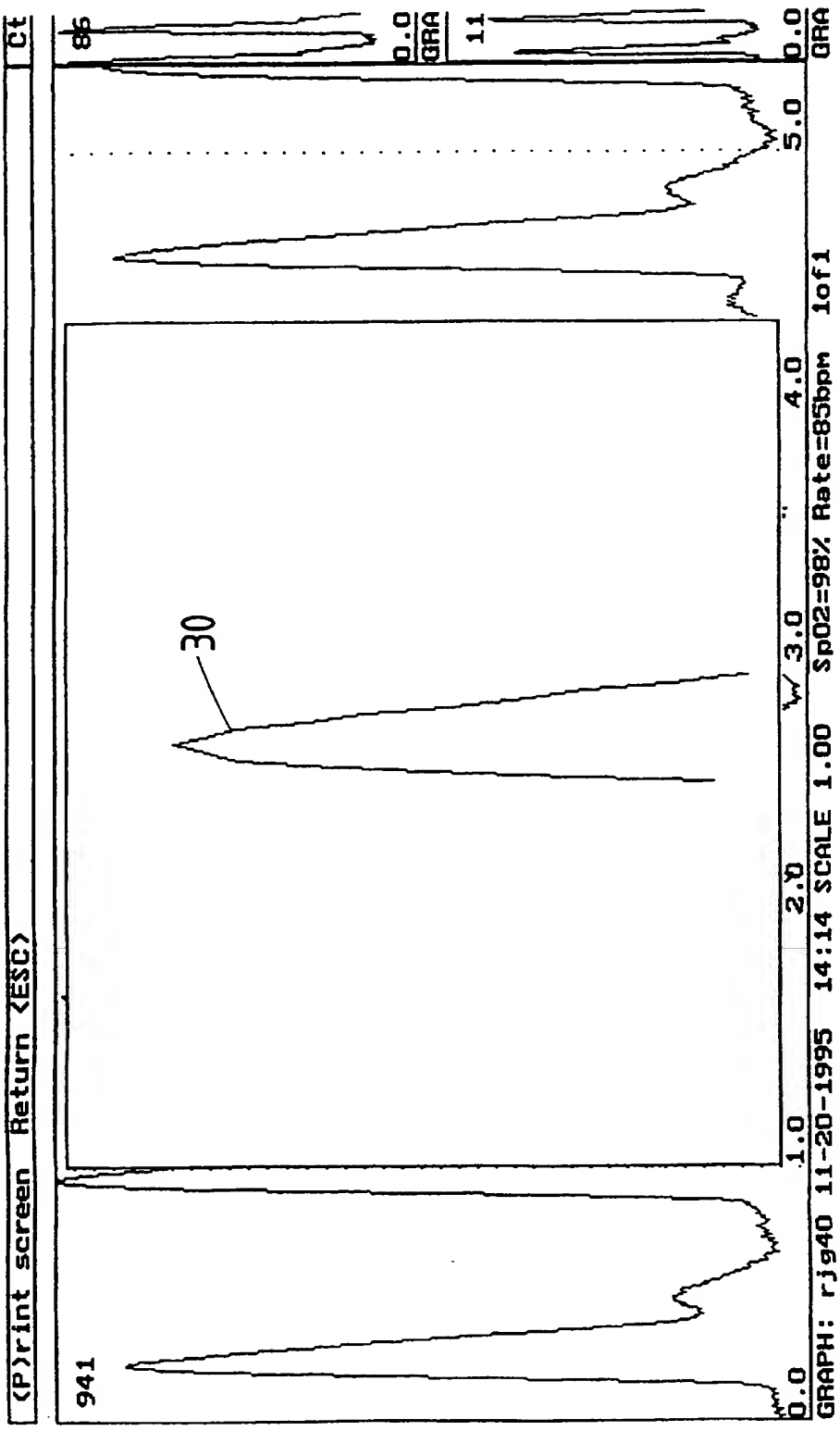
Ct
<P>rint screen Return <ESC>
941
86
11
0.0
GRA
5.0
4.0
3.0
2.0
1.0
30
GRAPH: rjg40 11-20-1995 14:14 SCALE 1.00 Sp02=98% Rate=85bpm 1of1

FIG. 8

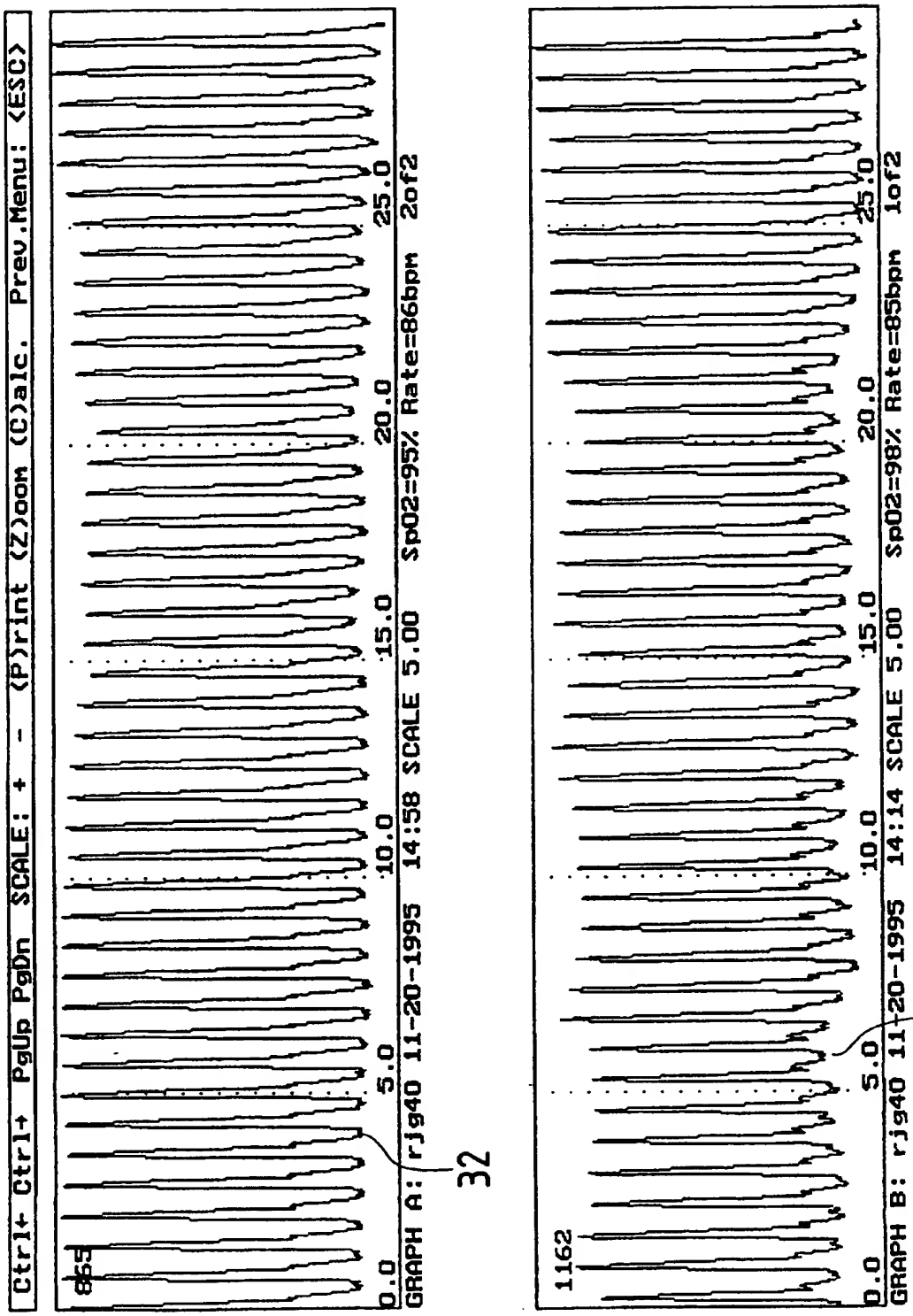
Ctrl← Ctrl→ PgUp PgDn SCALE: + - (P)rint (Z)oom (C)alc. Prev.Menu: <ESC>
865
0.0
5.0
10.0
15.0
20.0
25.0
GRAPH A: rjg40 11-20-1995 14:58 SCALE 5.00 SpO2=95% Rate=86bpm 2of2
32
1162
0.0
5.0
10.0
15.0
20.0
25.0
GRAPH B: rjg40 11-20-1995 14:14 SCALE 5.00 SpO2=98% Rate=85bpm 1of2
31

FIG. 9

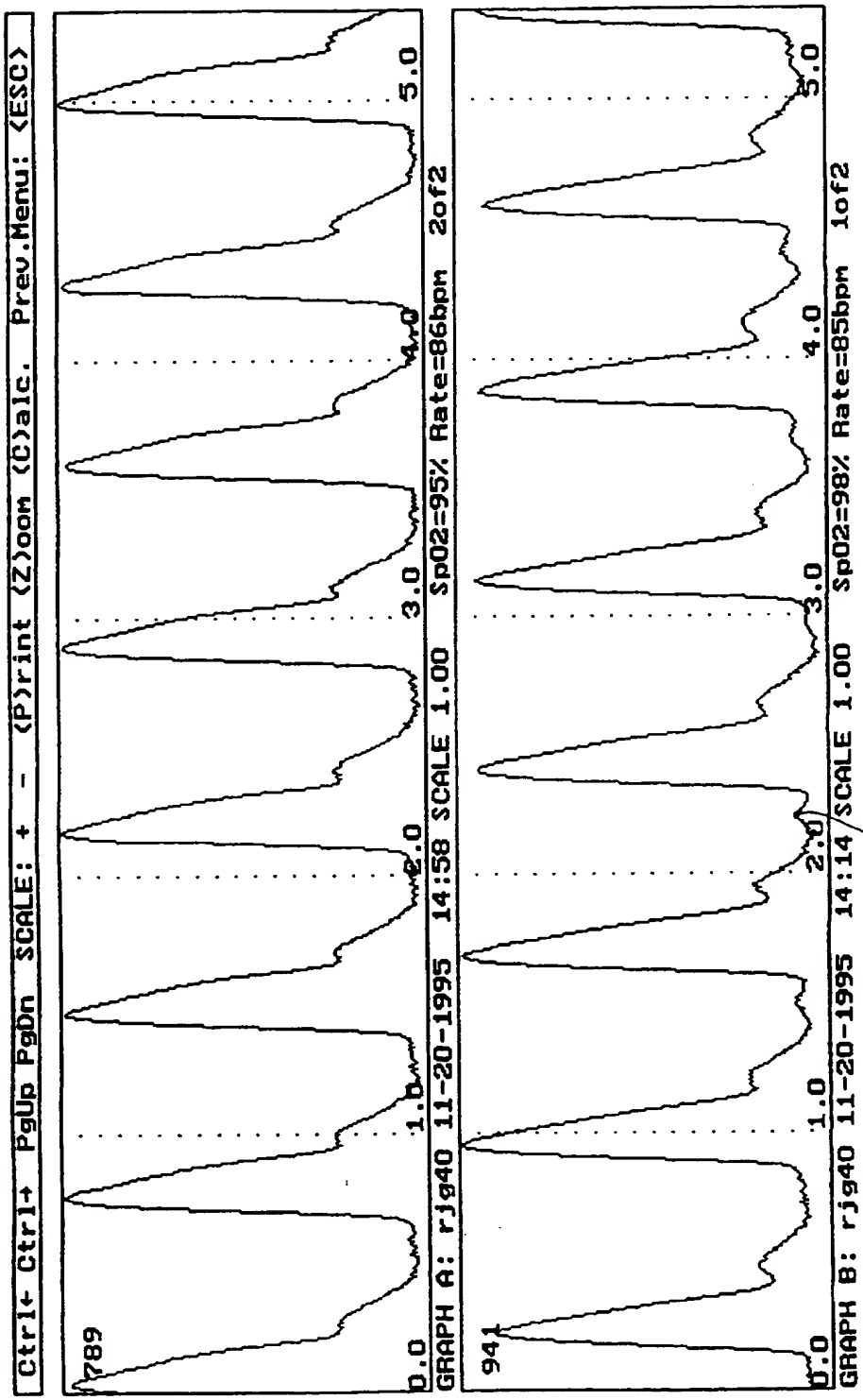
Ctrl← Ctrl→ PgUp PgDn SCALE: + - (P)rint (Z)oom (C)alc. Prev.Menu: <ESC>
789
0.0
1.0
2.0
3.0
4.0
5.0
GRAPH A: rjg40 11-20-1995 14:58 SCALE 1.00 Sp02=95% Rate=86bpm 2of2
941
0.0
1.0
2.0
3.0
4.0
5.0
GRAPH B: rjg40 11-20-1995 14:14 SCALE 1.00 Sp02=98% Rate=85bpm 1of2
33

FIG. 10

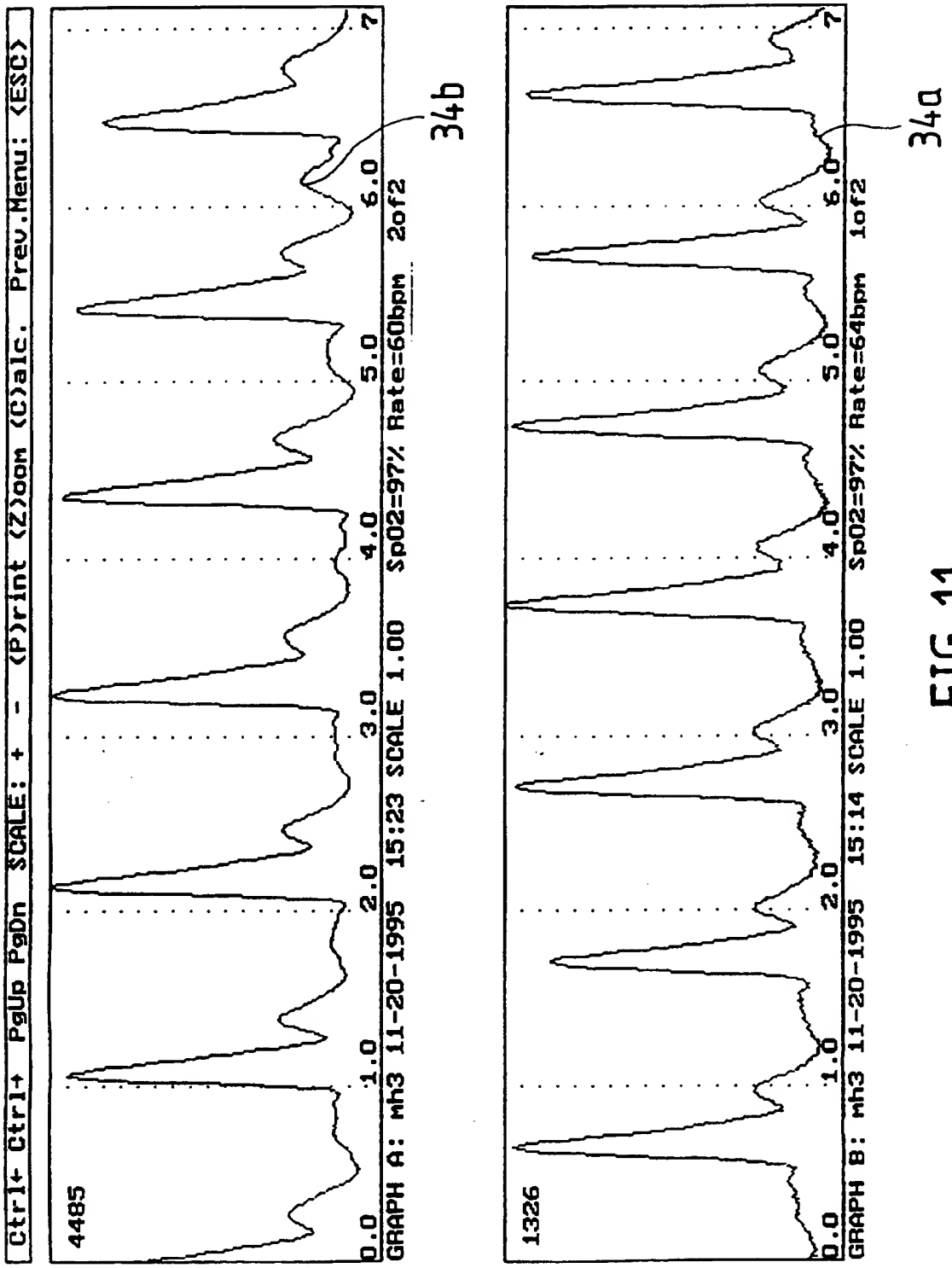
Ctrl← Ctrl→ PgUp PgDn SCALE: + - (P)rint (Z)oom (C)alc. Prev.Menu: <ESC>
4485
0.0
1.0
2.0
3.0
4.0
5.0
6.0
7
GRAPH A: mh3 11-20-1995 15:23 SCALE 1.00 Sp02=97% Rate=60bpm 2of2
34b
1326
GRAPH B: mh3 11-20-1995 15:14 SCALE 1.00 Sp02=97% Rate=64bpm 1of2
34a

FIG. 11

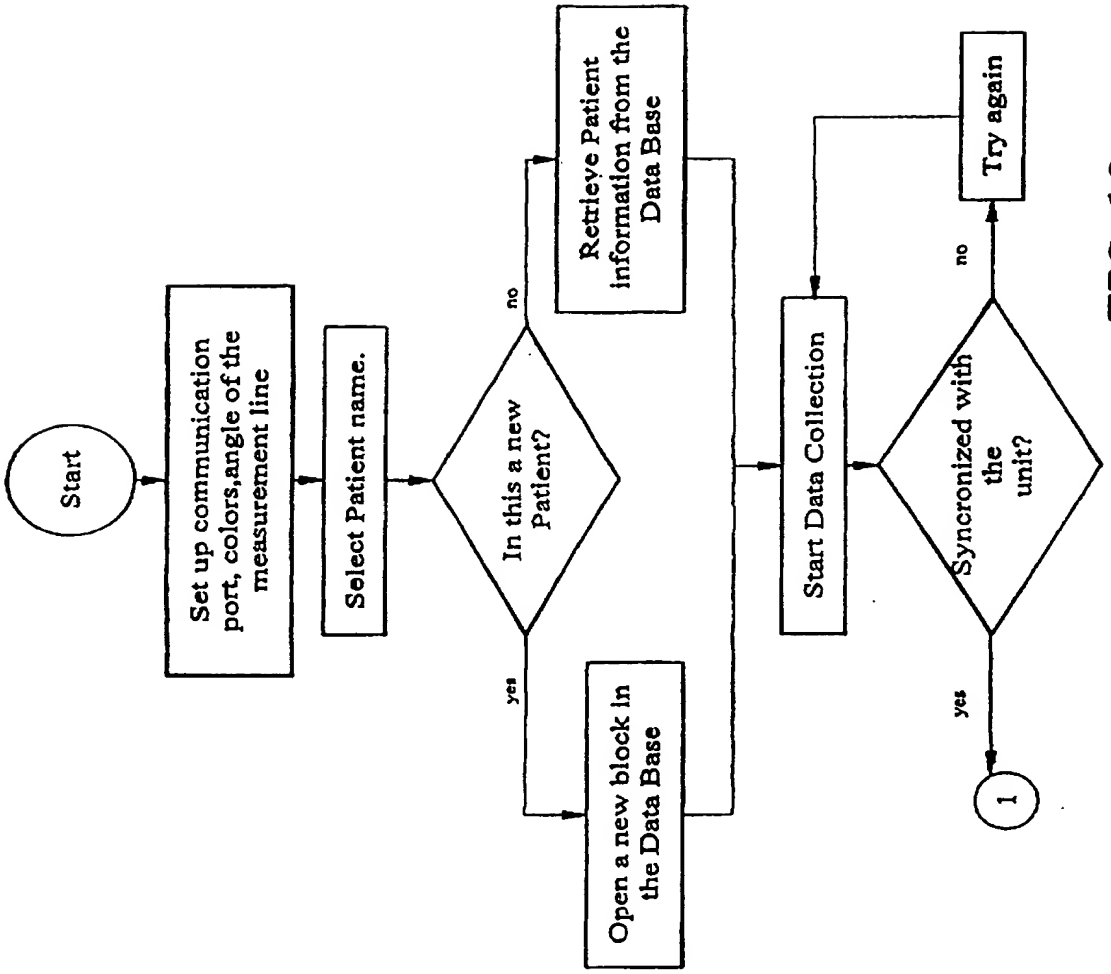
Start
Set up communication port, colors,angle of the measurement line
Select Patient name.
In this a new Patient?
no
Retrieve Patient information from the Data Base
yes
Open a new block in the Data Base
Start Data Collection
Syncronized with the unit?
no
Try again
yes
1

FIG 12a

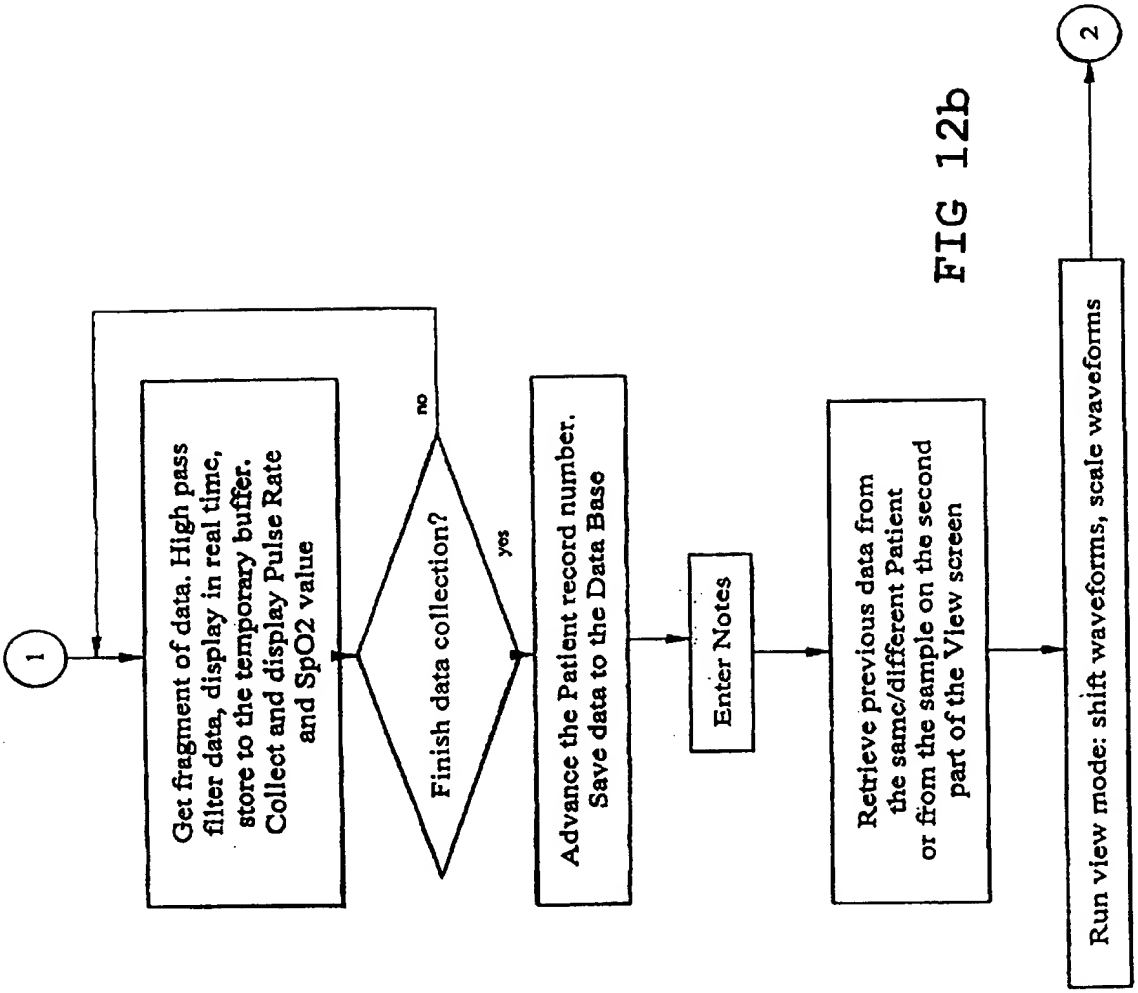
1
Get fragment of data. High pass filter data, display in real time, store to the temporary buffer. Collect and display Pulse Rate and SpO2 value
Finish data collection?
no
yes
Advance the Patient record number. Save data to the Data Base
Enter Notes
Retrieve previous data from the samc/different Patient or from the sample on the second part of the View screen
Run view mode: shift waveforms, scale waveforms
2

FIG 12b

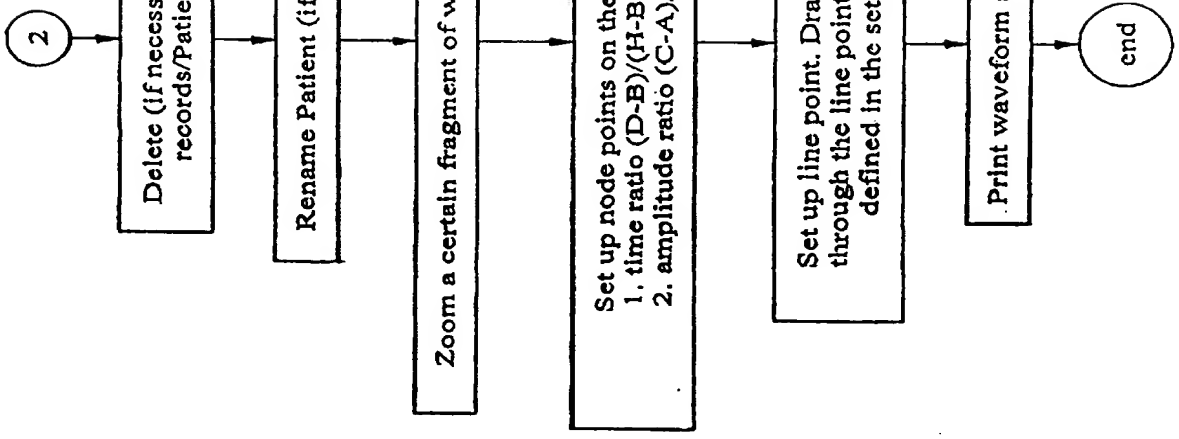
2
Delete (if necessary) some records/Patient data
Rename Patient (if necessary)
Zoom a certain fragment of waveform (if necessary)
Set up node points on the graph. Calculate:
1. time ratio (D-B)/(H-B)
2. amplitude ratio (C-A)/(E-A)
Set up line point. Draw angular line through the line point with an angle defined in the setup section
Print waveform and notes
end

FIG 12c

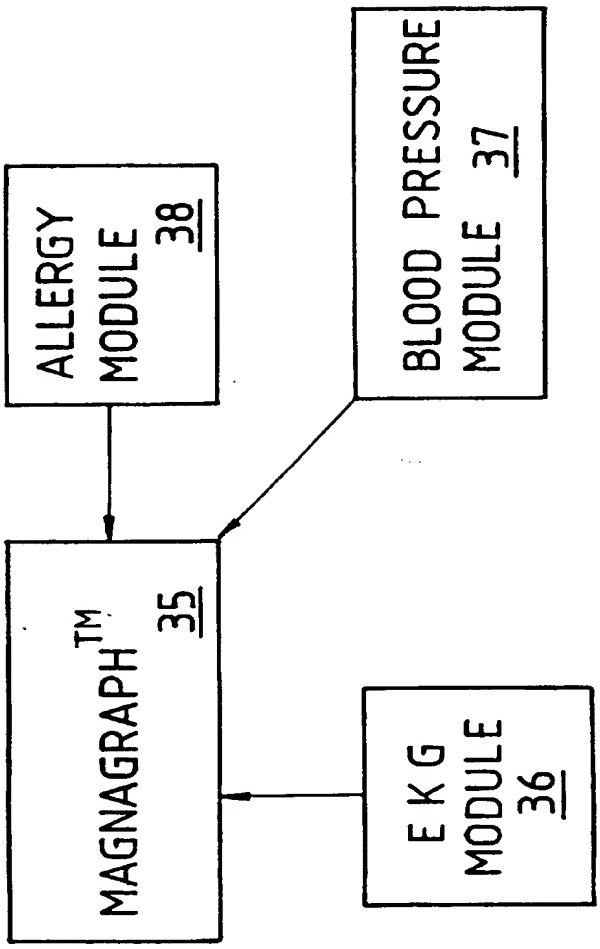
ALLERGY MODULE 38
BLOOD PRESSURE MODULE 37
MAGNAGRAPH™ 35
E K G MODULE 36

FIG. 13

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 96/00841

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61B 5/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC A61B 5/-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC A61B 5/02, 5/021, 5/024, 5/026, 5/0285, 5/029

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DERWENT: A61B 5ic AND oximet:
allerg: AND (skin: or derm:) AND (electr: or conduct:)
JAPIO: same as DERWENT

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92/21283 A1 (SOMANETICS CORPORATION) 10 December 1992 Figs. 1,2; entire document	1-19
X	WO 94/27492 A1 (NIMS, INC.) 8 December 1994 page 10 line 13 - page 11 line 4, page 25 line 11 - page 26 line 16, Figs. 2-13	1-19
X	WO 94/27493 A1 (SOMANETICS CORPORATION) 8 December 1994 Fig. 1, page 6 lines 3-20	1-19

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 March 1997	20.03.97
Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (06) 285 3929	Authorized officer PETER T. WEST Telephone No.: (06) 283 2108

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 96/00841

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 90/09146 A1 (AIR-SHIELDS, INC.) 23 August 1990 page 4 line 11 - page 5 line 6, page 9 lines 12-13, Figs. 1-4	1-19
X	AU 12063/88 A (FUJII) 1 September 1988 Figs. 1, 3, 4a, page 5 line 4 - page 9 line 20, entire document	1-19
X	AU 74638/91 A (PRECISION DIAGNOSTICS, INC.) 19 September 1991 Figs. 1, 2, abstract, page 17 lines 18-21, page 13 line 5 - page 29 line 24	1-19
X	AU 75189/91 A1 (STEPHENS) 18 March 1982 page 3 line 9 - page 5 line 1, page 6 lines 1-14, page 8 line 20 - page 9 line 10	1-19
X	AU 60745/80 A1 (BALIQUE) 1 October 1981 entire document	1-19
X	AU 33187/71 A (STEPHENS) 18 September 1970 Fig. 1, page 5 line 4 - page 8 line 11, entire document	1-19
X	US 4773422 A (ISAACSON et al.) 27 September 1988 Fig. 1, column 2 lines 16-68, column 2 lines 42-49	1-19
X	EP 286142 A2 (SUMITOMO ELECTRIC INDUSTRIES LIMITED) 12 October 1988 Fig. 1, abstract	1-17
X	WO 88/01149 A1 (PHYSIO-CONTROL CORPORATION) 25 February 1988 page 24 line 32 - page 25 line 6	1-17
X	EP 335356 A2 (NELLCOR INCORPORATED) 4 October 1989 Fig. 1, page 6 line 4 - page 7 line 59	1-17
X	US 5246002 A (PROSSER) 21 September 1993 Fig. 1, column 2 lines 7-37	1-17
X	US 5323776 A (BLAKELEY et al.) 28 June 1994 Fig. 1,column 4 line 26 - column 5 line 14	1-17
X	AU 12603/95 A (NELLCOR INCORPORATED) 22 June 1995 Fig. 2, page 2 line 33 - page 3 line 19, page 4 line 7 - page 8 line 17	1-17
X	AU 11537/95 A (OMRON CORPORATION) 10 August 1995 Fig. 15, page 11 paragraph 3, entire document	1-17

INTERNATIONAL SEARCH REPORT

Application No.
AU 96/00841

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AU 51768/90 A (RESEARCH TRIANGLE INSTITUTE) 7 September 1990 Fig. 1, page 7 line 23 - page 10 line 15	1, 2, 9-17
X	AU 13291/92 A (KRAIDIN et al.) 23 July 1992 Fig. 7, entire document	1, 2, 9-17
X	WO 92/22871 A1 (AKINYEMI) 23 December 1992 abstract, Fig. 4, page 1 line 10 - page 2 line 32, page 13 line 36 - page 14 line 37	1, 2, 9-17
X	AU 59618/94 A (MCINTYRE) 7 July 1994 Fig. 1, page 7 lines 3-32, page 8 line 23 - page 13 line 24	1, 2, 9-17
X	AU 90922/91 A (REGENTS OF THE UNIVERSITY OF MINNESOTA) 23 July 1992 Fig. 2, page 3 lines 4-23, page 4 line 6 - page 5 line 21	1, 2, 9-17
X	AU 42446/93 A (MCG INTERNATIONAL, INC.) 25 November 1993 Fig. 4	1, 2, 9-17
X	AU 27818/77 A (CORMIER) 15 February 1979 Fig. 1, page 9 line 25 - page 13 line 9	1, 2, 9-17
X	WO 93/19666 A2 (TELMED, INC.) 14 October 1993 Fig. 1, page 16 line 6 - page 22 line 6	1, 2, 9-17
X	AU 47198/93 A (UNIVERSITY COLLEGE OF SWANSEA) 17 February 1994 Fig. 1, entire document	1-11
P, X	AU 29118/95 A (NONIN MEDICAL, INC.) 11 January 1996 Fig. 14, page 2 lines 4-16, page 6 line 20 - page 7 line 20	1-11
X	US 4819657 A (KRAFT et al.) 11 April 1989 Fig. 3, abstract, entire document	1, 2, 9-17

INTERNATIONAL SEARCH REPORT

Application No.
AU 96/00841

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Derwent Abstract accession No. H4483W/29, SU 438412 A (KAUN MED INST) 30 January 1975	16
A	Derwent Abstract Accession No. J5112B/40, Class P31, SU 639525 (LITH EPIDEMOL MICRO) 26 February 1979	16
A	US 5408998 A (MERSCH) 25 April 1995 whole document	1-19

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 96/00841

Box I **Observations where certain claims were found unsearchable (Continuation f item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II **Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

See attached sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ N protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Internati nal Applicauon No.
PCT/AU 96/00841

Box II (cont.)

The international application does not comply with the requirements of unity of invention because it does not relate to one invention only. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1, 2 and 9-14 are directed to a general monitoring means adapted to process and display signals characteristic of blood flow.

2. Claims 3-8 further define the monitoring means of claim 1 to comprise a pulse oximeter. It is considered that this invention is merely a pulse oximeter. Claims 18 and 19 are also directed to a pulse oximeter.

3. Claim 15 further defines the monitoring means of claim 1 to comprise an ECG module. It is considered that this invention is merely an ECG monitor.

4. Claim 16 further defines the monitoring means of claim 1 to comprise an allergy module. It is considered that this invention is merely an allergy module dependant on blood flow.

5. Claim 17 further defines the monitoring means of claim 1 to comprise a pulse blood pressure module. It is considered that this invention is merely a pulse blood pressure monitor.

The feature common to all of the claims is the general monitoring means defined by claim 1. Such means is however, generic in the art of cardiovascular instrumentation.

Consequently the common feature does not constitute "a special technical feature" within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Since there exists no other common feature which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence, no technical relationship within the meaning of PCT Rule 13 between the different inventions can be seen.

Consequently it appears that, a posteriori, the claims do not satisfy the requirement of unity of invention.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.
PCT/AU 96/00841

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	9221283	CA	2110716	EP	597875		
WO	9427492	AU	69424/94	US	5588425		
WO	9427493	AU	70805/94	EP	700267	US	5482034
WO	9009146	AU	51959/90	CA	2046610	EP	460054
		US	5206807				
AU	12063/88	CA	1293535	EP	282210	JP	1124437
		US	4862894	JP	63214238		
AU	74638/91	US	5086776	WO	9113589		
AU	75189/91	CA	2040496	EP	454221	FI	911935
		JP	4228038	NL	9000996	NO	911519
		NZ	237940	PT	97493	US	5160753
AU	60745/80	AR	229019	BR	8004570	CA	1174281
		DK	3180/80	EG	14187	EP	23186
		ES	493716	ES	8105563	FI	802325
		FR	2461482	GR	69593	IN	154510
		JP	56027238	NO	802225	PL	225851
		PT	71596	TR	22788	US	4545387
		YU	1882/80	ZA	8004461		
AU	33187/71	US	3796213				
US	4773422						
EP	286142	JP	63252239	US	4867557		

INTERNATIONAL SEARCH REPORT

Patent Document Cited in Search Report		Patent Family Member					
WO	8801149	AU	77167/87	CA	1304503	EP	261787
		US	4869253				
EP	335356	CA	1327402	FI	891493	JP	2203843
		US	4869254	US	5078136		
US	5246002						
US	5323776						
AU	12603/95	WO	9516388	EP	734223	CA	2179023
		US	5560355				
AU	11537/95	CN	1111499	EP	666055	JP	7255688
		US	5539706				
AU	51768/90	US	4905705	WO	9009757		
AU	13291/92	US	5183051	WO	9211804		
WO	9222871	GB	9112458	AU	18903/92	EP	589923
		GB	9111413				
AU	59618/94	US	5291895	CA	2152905	EP	680274
		WO	9414371	CA	1311016	EP	204394
		JP	61279229				
AU	90922/91	EP	564492	US	5211177	WO	9211805
		US	5316004				
AU	42446/93	EP	645981	US	5337752	WO	9322970
AU	27818/77	CA	1088635	DE	2737519	GB	1588891
		IL	52667	JP	53026489	US	4094308
		US	4289141				
WO	9319666	AU	39691/93	US	5265613		
AU	47198/93	WO	94/03102				
WO	9600518	AU	29118/95	US	5490523		

INTERNATIONAL SEARCH REPORT

Patent Document Cited in Search Report		Patent Family Member			
US	4819657				
SU	438412				
SU	639525				
US	5408998	AU	18424/95	WO	9524150

END OF ANNEX